K130196

510(k) Summary

FEB 2 7 2013

ArthroCare® Corporation

SpeedLock® Knotless Fixation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
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Contact Person:	Cheryl Frederick Director, Regulatory Affairs
Date Prepared:	January 25, 2013

Device Name

Proprietary:	SpeedLock® Knotless Fixation System
Common:	Bone Anchor, Fastener, Fixation, Soft Tissue
Classification:	Class II
Product Code:	MBI
CFR Section:	21 CFR 888.3040

Predicate Device

This 510(k) relates to a modification to the SpeedLock Knotless Fixation System cleared under K111044 on August 9, 2011.

Description

The SpeedLock Knotless Fixation System is a bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. With this anchor, surgical knots are not necessary for the fixation of soft tissue to bone.

The SpeedLock consists of two primary parts: a 3.4 mm PEEK bone anchor and a disposable anchor inserter, which is preloaded with the anchor. The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized. Both the anchor and inserter are designed for single use only.

The SpeedLock System also includes associated instruments for implanting the anchor into bone.

The design modifications include aligning the shape and size of the windows at the distal end of the anchor and adding a flat surface to the internal crossbar against which the anchor plug may rest once deployed. The modifications do not alter the overall device characteristics or the manner in which the device is used, and there are no changes to the devices cleared indications for use.

Intended Use/Indications For Use

The SpeedLock Knotless Fixation Implant is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:

Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon attachment
Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Non-Clinical Data

Design Verification testing was performed to demonstrate that the modifications to the cleared SpeedLock Knotless Fixation System do not alter the device's intended use or performance. Insertion strength and pull-out strength testing in a simulated bone substrate was also conducted.

The test results demonstrate that the modified SpeedLock Knotless Fixation System meets its design, performance, and safety specifications.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the modified SpeedLock Knotless Fixation System performs as intended and mechanical properties are substantially equivalent when used in accordance with its labeling.

Since the modified device's intended use and technological characteristics are the same as those for the previously cleared device, we do not believe that the modification to the SpeedLock Knotless Fixation System raises any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

ArthroCare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

Re: K130196
Trade/Device Name: SpeedLock® Knotless Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: January 25, 2013
Received: January 28, 2013

Dear Ms. Frederick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130196

Device Name: SpeedLock® Knotless Fixation System

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices